UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,157	10/13/2005	Patrick Trotter	ETH5231USPCT	6570

27777 7590 11/15/2007

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,157	TROTTER ET AL.	
	Examiner	Art Unit	
	Ronald T. Niebauer	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7-10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-6, 11 and 13-22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group VIII (claims 1-6,11,13-22) and the species of antimicrobial agent for the agent in the reply filed on 9/21/07 is acknowledged. A species of peptide sequence as required on page 4 of the restriction requirement was not elected in the reply. A telephone call to applicants representative Theodore Shatynski on 10/3/07 resulted in election of SEQ ID NO:19 (Gly-Arg-Gly-Asp) for the peptide. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-10,12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/21/07 and telephone call of 10/3/07.

Claims 1-6,11,13-22 are under consideration. Since claims 3-6,11,13-22 are multiple dependent claims (see below), the claims are objected to and have not been further treated on the merits (see MPEP section 608.01(n)).

The procedure for examination of Markush type claims is highlighted in MPEP section 803.02:

> Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.
>
> The examination will be extended to the extent necessary to determine patentability

of the Markush-type claim.

In the instant case, the claim to the elected species (claim 11) is objected to as being a multiple dependent claim. A search of the elected species in relation to the claims treated on the merits (claims 1-3) resulted in art that anticipated the elected species. Claims drawn to nonelected species are held withdrawn.

Claim Objections

Claims 4-6,11,13-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). In particular, a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. In the instant case, claim 4 (for example) is a multiple dependent claim as it recites claim 1,2 or 3 and it improperly depends from claim 3 which itself is a multiple dependent claim since it refers to claim 1 or 2. **Accordingly, the claims have not been further treated on the merits.**

Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 appears to recite a property of the protease. However, the protease is not a part of the wound dressing (the sequences can be cleaved by the protease but the protease does not necessarily need to be present). Claim 3 appears to recite a property of the

polymer. However, the recited property does not limit the claim to a particular structure and does not limit the claim (see MPEP section 2111.04).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional

characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to wound dressing comprising a matrix comprising oligopeptide sequences which are cleavable by a protease associated with wound fluid.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

The oligopeptide sequences are described as being cleavable by a protease. The claims (such as claim 7-12) give examples of several oligopeptide sequences. However, nearly every protein is cleavable by a protease. For example, Matthews (Biochemistry 1996) teach numerous proteases such as trypsin, pepsin thrombin, and papain that would cleave an oligopeptide sequence. For example trypsin cleaves when R1 is Lys or Arg (see Table 5.4 of Matthews). If one considered a 10 amino acid peptide (R1-R10) oligomer with either Lys or Arg at R1 and any other amino acid except proline at R2 and any amino acid at the other positions there would be at least 20^8 (over 2 billion) possible peptides. Even though approximately 30 different oligopeptide sequences are recited in the specification, the recited peptides do not represent the genus. One of skill in the art would not recognize that the applicant was in possession of wound dressings with oligopeptide sequences of the scope of the genus of claim 1.

The dressing is described as a matrix comprising polymers and a therapeutic agent. The specification (page 5) provides examples of numerous polymers. However, no examples are provided of a matrix comprising polymers and a therapeutic agent. An example appears on page 9 lines 19-25 which recite specific oligopeptide sequences and a specific polymer. This example does not represent the claimed invention because the example does not recite a therapeutic agent. Therapeutic agents are a component of the wound dressing. The agents can be a variety of things (claim 13, page 10). However, no specific examples of wound dressings are provided. Although examples have been provided of components of the wound dressing no examples have been provided of a wound dressing as claimed. The example on page 9 lines 19-25 does not recite any agent.

There is substantial variability in the genus. Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 1 recites that the protease is associated with wound healing. Claim 1 recites that the wound dressing is such that the rate of release of the therapeutic agent increases in the presence of the protease. However, no common core structure is recited for the protease of claim 1. One of skill in the art would not recognize which proteases or wound dressings would fall within the scope of the claims.

(5) Method of making the claimed invention:

The specification does not describe any specific embodiments of wound dressings nor methods of making them.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1 is/are broad and generic, with respect to all possible wound dressings encompassed by the claims. The possible structural variations are limitless to any agent, polymer, and peptide meeting the claim limitations. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the components beyond those components specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of wound dressings embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sojomihardjo et al. (WO 96/40829).

Sojomihardjo teach (claim 18 page 53) an article comprising a crosslinked polypeptide (i.e. a matrix comprising polymers – polypeptides are polymers) having a biologically active material (i.e. therapeutic agent) entrapped therein. Sojomihardjo teach the active material as an antibiotic (which is the elected agent species) (page 20 line 29-31, more generally on page 17 line 25) in the matrix of cross-linked protein (page 20 line 23-25). Sojomihardjo teach GRGD (which is identical to the elected peptide sequence) (page 15 line 26) as a crosslinkable peptide. Sojomihardjo teach the compositions as wound dressings (abstract last sentence, claim 6).

It is noted that claim 1 recites 'that the rate of release if the therapeutic agent increases'. Since the art meets the structural limitations of the claim, it must necessarily meet the functional limitations (MPEP section 2112.01 II). Claim 2 appears to recite a property of the protease. However, the protease is not a part of the wound dressing (the sequences can be cleaved by the protease but the protease does not necessarily need to be present) and does not further limit the claim. Claim 3 appears to recite a property of the polymer. However, the recited property does not limit the claim to a particular structure (see MPEP section 2111.04).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,7-17 (10/2/07 claim set) of copending Application No. 10/554,375. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'375 teach a wound dressing comprising a therapeutic agent and a matrix comprising polymers comprising oligopeptide sequences (claim 1 for example) which reads on claims 1-3 of the current invention.

It is noted that claim 1 recites 'that the rate of release if the therapeutic agent increases'. Since the art meets the structural limitations of the claim, it must necessarily meet the functional limitations (MPEP section 2112.01 II). Claim 2 appears to recite a property of the protease. However, the protease is not a part of the wound dressing (the sequences can be cleaved by the

protease but the protease does not necessarily need to be present) and does not further limit the claim. Claim 3 appears to recite a property of the polymer. However, the recited property does not limit the claim to a particular structure (see MPEP section 2111.04).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 (3/24/05 claim set) of copending Application No. 10/529,156. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'156 teach a wound dressing comprising a therapeutic agent and a layer comprising oligopeptide sequences (claim 1,3 for example) which reads on claims 1-3 of the current invention. Since elastin is a polymer (i.e. a protein is a polymer of amino acids), '156 meets the limitations of the current claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13,15-18 (3/3/05 claim set) of copending Application No. 10/497,442. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'442 teach a wound dressing comprising a therapeutic agent and a barrier layer (claim 1). The barrier layer comprises proteins (claim 13) which are polymers of amino acids, so '442 meets the limitations of the current claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 (5/19/06 claim set) of copending Application No. 10/579,897. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'897 teach a wound dressing comprising a therapeutic agent and a polymer and a linker group (claim 1). The linker group is specifically taught to be an oligopeptide sequence (claims 7-13 for example).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 directed to an invention not patentably distinct from the claims listed above of commonly assigned 10/554,375; 10/529,156; 10/497,442; and 10/579,897. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/554,375; 10/529,156; 10/497,442; and 10/579,897, discussed above,

would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

The examiner has identified four copending Applications which have been rejected under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rtn

11/13/07
ANISH GUPTA
PRIMARY EXAMINER